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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,849	03/29/2001	Gordon G. Wong	GIN-6403	8494

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/12/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,849

Applicant(s)

WONG ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1-592. Claims 1-6, drawn to nucleic acid, vector and host cell, classified in class 536, subclass 23.1 et al.;
- 593-1184. Claim 7, drawn to method make protein, classified in class 435, subclass 69.1;
- 1185-1776. Claim 8, drawn to protein, classified in class 530, subclass 350;
- 1777-2368. Claim 9, drawn to antibody, classified in class 530, subclass 387.1;
- 2369-2960. Claims 10, 12 and 13, drawn to protein assay, classified in class 435, subclass 7.1;
- 2961-3552. Claims 11, 14 and 15, drawn to nucleic acid assay, classified in class 435, subclass 6;
- 3553-4144. Claim 16, drawn to protein activity assay, classified in class 435, subclass 194;
- 4145-4736. Claim 17, drawn to nucleic acid screen for modulating compound, classified in class 435, subclass 4;
- 4737-5328. Claim 18, drawn to protein screen for modulating compound, classified in class 435, subclass 7.21;
- 5329-5920. Claim 19, drawn to method treat with compound that modulates expression of polynucleotide, classified in class 514, subclass 44;
- 5921-6512. Claims 20 and 21, drawn to method treat with compound that modulates expression or activity of protein, classified in class 514, subclass 2.

2. Inventions 1185-1776 and 593-1184 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product protein can be made by automated synthesis or isolation from nature.

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3. Inventions (1-592, 1185-2368) and 2369-5328 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used as templates in amplification assays and the proteins and antibodies can be used as label carriers in nucleic acid assays.

4. The polynucleotide, protein and antibody products of groups 1-592, 1185-2368 and 593-1184 can be shown to be distinct, each from the other. Although the polynucleotides and proteins are related as the claimed protein is asserted to be encoded by the claimed nucleic acid molecule, they are distinct inventions in that they are structurally and functionally distinct chemical compounds. The proteins can be made by another and materially different process without use of the nucleic acid, for example, by chemical synthesis or purification from a natural source. Similarly, making the nucleic acid does not require use of the protein or antibody and the antibody can be made with a synthetic epitope not requiring the protein. The antibody and protein products are structurally and functionally distinct from one another in that while the former contains amino acids and sugars, the latter may or may not also contain sugars and while the antibody is primarily a binding molecule, proteins have many functions including catalysis and skeletal support.

5. The methods of groups 2369-6512 can be shown to be distinct each from the other as they have different starting materials, different method steps, different operating modes and different results. These methods can be shown to be distinct from the products of groups 1-592 and 1185-2368 as each of the products either is not used in the methods or has uses unrelated to the methods. For example, the polynucleotides can be used as probes or to make the proteins, the proteins can be used to make antibodies or for screening potential modulating compounds.

6. Additionally, each of groups 1-6512 is defined by a unique nucleotide sequence identified by its SEQ ID NO:. Different nucleotide sequences are structurally and functionally distinct chemical compounds unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35

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U.S.C. 121 and are subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq..

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and the sequence and prior art searches required for the different groups are not coextensive thus constituting a search burden restriction for examination purposes as indicated is proper.

8. Applicant is required to elect an invention group by its group number and, as an accuracy check, by its **SEQ ID NO:**, to which prosecution of the claims will be restricted.

This is not an election of species.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.


Stephanie Zitomer, Ph.D.

July 5, 2002

STEPHANIE ZITOMER
PRIMARY EXAMINER